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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,036	07/05/2001	Mark Leslie Smythe	36677.29	3406
27683	7590	12/02/2005	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 12/02/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/806,036	<b>Applicant(s)</b> SMYTHE ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-19, 32-35, 39, 40 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-19, 32-35, 39, 40 and 44-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 8-19, 32-35, 39, 40 and 44-52 are pending.

Applicants' amendment filed on September 02, 2005 is acknowledged. Applicants' response has been fully considered. Claims 8-19, 32-35, 39, 40 and 44-52 have been amended. Thus, claims 8-19, 32-35, 39, 40 and 44-52 are examined.

### ***Withdrawn Claim Rejections - 35 USC § 112***

2. The previous rejection of claims 12, 19, 32, 39 and 50 under 35 U.S.C. 112, second paragraph, regarding the term "derivatized", "Z is any group which allows the formation of a covalent carbon-nitrogen bond", or if A1 is a reversible substituent, cleaving the groups A1 and A2 to yield the desired cyclic peptide of Formula I", is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 21-22 of the amendment filed September 02, 2005.

### ***Maintained Claim Objection***

3. Claim 19 remains objected to because the claim contains recitation of a compound of formula (a), which has undefined R<sup>6</sup>.

### **Response to Arguments**

Applicants indicate the claim has been amended to reflect a six-member aromatic ring structure (page 20 of the response). The response has been considered, however, the argument is not found persuasive because the formula (a) contains R<sup>6</sup>. Since the formula (a) is directed to a six-member aromatic ring structure, which should be indicated in the claim.

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***Maintained Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 8-19, 32-35, 39, 40 and 46-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 23, 30, 31 and 35 of co-pending application 09/787,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 8-19, 32-35, 39, 40 and 46-52 in the instant application disclose a method of synthesis of a cyclic peptide or peptidomimetic compound of General Formula I or II, comprising preparing a linear peptide of General Formula III having A1 and A2, wherein A1 is N-substituent on the peptide backbone or a chemical moiety that forces a cis conformation, and A2 is a group of atoms comprising a reactive functionality to form an initial large cyclic peptide prior to ring contraction to the desired substituted cyclic peptide, activating the C-terminus to form a large cyclic peptide, subjecting the large cyclic peptide to ring contraction to the desired substituted cyclic peptide, and deprotecting the substituted cyclic peptide. This is obvious variation in view of claims 1-21, 23, 30, 31 and 35 of the co-pending application which disclose a method of synthesis of a linear, cyclic peptide or on-resin cyclization of a peptide molecule, comprising linking a cyclic aromatic

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or alkyl auxiliary compound to an amine nitrogen atom. Since both sets of claims are directed to a method of synthesis of a cyclic peptide or peptidomimetic compound either in solution or on a solid support, comprising preparing a linear peptide having A1 and A2 by linking a cyclic aromatic or alkyl auxiliary compound to an amine nitrogen atom, and cyclizing the peptide. Therefore, claims 8-19, 32-35, 39, 40 and 46-52 in instant application and claims 1-21, 23, 30, 31 and 35 of the co-pending application are obvious variations of a method of synthesis of a cyclic peptide or peptidomimetic compound either in solution or on a solid support, comprising preparing a linear peptide having A1 and A2, where A1 and A2 are used to facilitate the cyclization reaction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Response to Arguments

Applicants indicate they would defer submission of a terminal disclaimer until such time all claims are allowed in the present case. The response has been considered, and the rejection is maintained.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-19, 32-35, 39, 40 and 44-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claims 8-19, 32-35, 39, 40 and 44-52 are indefinite because of the use of the terms “P is an amino acid” and “preparing a linear peptide of General Formula III”. The terms cited render the claim indefinite, it is not clear how a peptide, which is made by condensation of at least two amino acid residues and contains at least one peptide bond (CO-NH), can be an amino acid. Claims 9-19, 34-35, 39, 40 and 44-52 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

*Response to Arguments*

Applicants indicate claims 8, 32 and 33 were clarified to recite that P is “an amino acid or a linear peptide of 2 to 15 monomers” which addresses the clarity issue with respect to the word monomer (page 21 of the response).

The response has been considered, however, the argument is not found persuasive because P is a peptide of 2 to 15 monomers, where the monomer is an amino acid. P cannot be an amino acid due to the definition of the peptide (see Voet et al., Biochemistry page 62-63, Fig. 4-3).

7. Claims 8-19 and 44-50 are indefinite because the claim lacks essential steps to synthesize cyclic peptidomimetic compound of General Formula I or General Formula II, and cyclic peptide of General Formula II. The steps of a)-d) cited in the claims do not indicate a peptidomimetic compound is used in the synthesis, nor cites the peptide is linked to the solid support. Claims 9-19 and 44-50 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

8. Claims 46 and 48 are indefinite because the structure of A2 does not conform the elected structure of a six-member aromatic ring with X being oxygen, sulfur, CH<sub>2</sub>O-, CH<sub>2</sub>S; Y being

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electron-withdrawing groups; and Z being a group to form C-N bond, e.g., no X group is in the third and fourth compounds, and where is R' (peptide) attached.

***Conclusion***

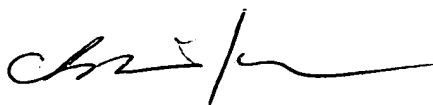
9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

November 17, 2005